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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,531	07/01/2003	Andrew Kerr	Kerr-5 CIP 3	5255
1218	7590	02/03/2006	EXAMINER	
CASELLA & HESPOS 274 MADISON AVENUE NEW YORK, NY 10016			BLANCO, JAVIER G	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 02/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/612,531

Applicant(s)

KERR, ANDREW

Examiner

Javier G. Blanco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7/1/2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5/27/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of claim 7 in the reply filed on August 4, 2005 is acknowledged.

Election/Restrictions

2. Applicant's election of **stent/graft: Species O** (Figures 25-29), **end-to-end connection: Species A** (Figures 1 and 2), and **deployment: Species B** (Figures 38-40) in the reply filed on August 4, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
3. Claim 6 (end-to-end connection: Species C, embodied in Figure 4A) is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on August 4, 2005.

Priority

4. Claims 1-5 and 7 are directed to subject matter (i.e., stent/graft assembly having a pre-deployment orientation in which second ends of the graft and stent extend in opposite direction, and having a post-deployment orientation in which said second ends of said graft and stent extend in a common direction) that was introduced for the first time in the present application, filed July 1st, 2003. It should be noted that a "substantially end-to-end relationship/connection"

between a graft and a stent in a stent/graft assembly is subject matter well known in the art. Thus, the effective filing date for the subject matter of claims 1-5 and 7 is July 1st, 2003.

Drawings

5. With some Figures (e.g., Figure 16) it is very difficult to discern between a stent and a graft.
6. Figure 40 was not provided in the instant application (the Examiner assumes Figure 40 depicts the post-deployment orientation of stent/graft assembly 810, or, the final step(s) of deployment of stent/graft assembly 810).
7. Figure 39 is objected to under 37 CFR 1.83(a) because it fails to show the relationship between first bifurcated leg 815-1 in relation to second bifurcated leg 815-2 as described in the specification (see paragraph 0107). It is very difficult to distinguish between first bifurcated leg 815-1 and second bifurcated leg 815-2. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d).

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the

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renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

8. Claims 1 and 2 are objected to because of the following informalities:
- a. Regarding claim 1, please substitute "relationship" (see line 4) with --connection-- (as shown in claim 1 at line 6: "end-to-end connection"). Appropriate correction is required.
 - b. Regarding claim 2, please substitute "first surface" (see line 3 and line 4) with --first peripheral surface--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-4 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Tanner et al. (US 5,944,750 A).

Referring to Figures 1A, 1B, 2A, 2B, 3-7, and 9, Tanner et al. disclose a stent/graft assembly (e.g., either proximal stent/graft 10, distal stent/graft 20, or tubular stent/graft 3). Said

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assembly comprising a substantially tubular graft (e.g., Figures 1B and 2B: stent/graft 3 has a main body and bifurcated legs) having opposite first (i.e., main body) and second ends (i.e., bifurcated legs) and a substantially tubular stent (Figure 5: stent 30; see column 9, lines 32-44) having opposite first (end facing bifurcated legs) and second (end facing or exposed to the vessel) ends. The graft could be either cylindrical (Figures 3 and 4) or bifurcated (Figures 1A, 1B, 2A, and 2B). Said first end of said stent being connected in a substantially end-to-end connection with said first end of said graft, said assembly having a pre-deployment orientation (e.g., Figure 1B) in which said second ends of the graft and stent extend in opposite direction from the substantially end-to-end connection, and having a post-deployment orientation (e.g., Figure 2B: bifurcated legs are invaginated) in which said second ends of said graft and stent extend in a common direction from the substantially end-to-end connection between said graft and said stent. A peripheral surface of said graft is in substantially face-to-face engagement with an outer circumferential surface of said stent in said post-deployment orientation, and the second end of the graft extending axially beyond the second end of the stent in said post-deployment orientation (see, for example, Figure 2B).

It should be noted that the attachment cuff (characters 12 and 21) is disclosed as an attachment means (see column 8, lines 62-67; column 9, lines 11-18), and could be interpreted as a stent having a flared end and a tubular end in end-to-end relationship with the main body of a bifurcated graft. As disclosed throughout the document, once said attachment means (i.e., cuff or stent) is firmly secured to the vessel wall, the graft is then invaginated.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tanner et al. (US 5,944,750 A).

Tanner et al. disclose the invention as claimed in claims 1-4 and 7 (see 102(b) rejection above). Although Tanner et al. disclose the second end of the graft as extending axially beyond the second end of the stent in said post-deployment orientation (see, for example, Figure 2B), they did not particularly disclose the second end of the stent as extending axially beyond the second end of the graft in said post-deployment orientation. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have extended the second end of the stent axially beyond the second end of the graft in said post-deployment orientation, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. *In re Einstein*, 8 USPQ 167. It would also have been obvious to extend said second end of the stent beyond the second end of the graft in view of the advantage of better attachment/affixation of the stent to the wall of the blood vessel.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

October 15, 2005



CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
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